REMARKS

Entry of this amendment is respectfully requested. No new matter is added by the amendment, because the amended application is fully supported by the application as filed. In particular, new claim 21 is essentially claim 8 rewritten in independent form, and many of the new claims, although new, parallel prior dependent claims but are now dependent on claim 21 instead of former claim 1.

Claims 21-38 are in this application, claims 1-20 having been canceled and claims 21-38 having been added by this amendment.

Previous claims 1-20 were subject to a restriction requirement under 37 CFR 1.499, with claims 1-9 elected with traverse, and claims 1-9 were rejected under 35 USC 102(b). The restriction requirement and the rejections are respectfully traversed as applied to the amended claims.

The restriction requirement

Previous claims 1-20 were subject to a restriction requirement under 37 CFR 1.499, with the Examiner stating that the inventions of the four groups of claims did not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lacked the same or corresponding technical features for the reason that the composition was anticipated by the references cited in the rejections.

Applicants respectfully submit that claims 21-38 now presented do relate to a single inventive concept under PCT Rule 13.1 because they share the same technical feature, namely the arabinogalactan protein composition of claim 21; and that this composition is patentable. Thus, claims 21-28 are directed to the composition (with claim 28 being directed to an injectable formulation comprising the composition), claims 29-37 are directed to methods of treatment using the composition, and claim 38 is directed to a method of making the composition.

For the avoidance of unnecessary delay, though, if the Examiner believes that claims 21-38 do not relate to a single inventive concept under PCT Rule 13.1 and are therefore subject to a restriction requirement under 377 CFR 1.499, Applicants elect for examination claims 21-28 directed to the composition itself, but this requirement is traversed for the reason that claims 21-38 share the same technical feature, namely the arabinogalactan protein composition of claim 21.

The 35 USC 102(b) rejections

Claims 1-9 were rejected under 35 USC 102(b) as being anticipated by:
Dan Bensky et al. (Reference 19 from the IDS),
Hson-Mou Chang et al. (Reference 20 from the IDS),
Chu et al. (Reference 21 from the IDS),
CN 1047806, and
EP 0 441 278.

In each case, the Examiner asserts that the references anticipate the claimed subject matter by teaching an extract from the claimed plant "which inherently has the same composition in it since it is extracted from the same plant." These rejections are respectfully traversed as to claims 21-38.

Applicants note that claim 21 requires an arabinogalactan protein composition having a weight average molecular weight of at least 100 kiloDaltons, isolated from a purified arabinogalactan composition isolated from *Astragalus membranaceus*; and that dependent claims 22-38 require either additional features in the composition, or specify a method of use, or specify a method of making the composition.

Dan Bensky et al. discloses Radix Astragali (the root of *Astragalus membranaceus*), and specifies a number of its uses in traditional Chinese medicine. It refers to "decoctions of the root of *Astragalus membranaceus*" and injections of these decoctions into laboratory animals. However, even if Dan Bensky et al. was considered to disclose a purified arabinogalactan composition isolated from *Astragalus membranaceus*, and this is disputed because there is no showing of purification, there is no indication in Dan Bensky et al. of the arabinogalactan protein composition having a weight average molecular weight of at least 100 kiloDaltons claimed in claim 21 (and it is clearly not inherent because Applicants' own preparation requires the separation of this material from a purified arabinogalactan composition). Withdrawal of the rejection is requested.

So what?

Hson-Mou Chang et al. discloses "Huangqi" (the root of *Astragalus membranaceus*), and specifies a number of its uses in traditional Chinese medicine. It refers to its decoctions, and their effects when injected into laboratory animals and in some human clinical studies. However, even if Hson-Mou Chang et al. was considered to disclose a purified arabinogalactan composition isolated from *Astragalus membranaceus*, and this is disputed because there is no showing of purification, there is no indication in Hson-Mou Chang et al. of the arabinogalactan protein composition having a weight average molecular weight of at least 100 kiloDaltons claimed in claim 21. Withdrawal of the rejection is requested.

So what?

Chu et al. discloses a partially purified fraction (F3) with an estimated molecular weight of 20,000-25,000 derived from *Astragalus membranaceus*, and states that it was found to possess a potent immunorestorative activity *in vitro* and that it had the ability to aborogate [*sic*] the local xenogeneic graft versus host reaction in a mouse model. However, even if Chu et al. was considered to disclose a purified arabinogalactan composition isolated from *Astragalus membranaceus*, there is no indication in Chu et al. of the arabinogalactan protein composition having a weight average molecular weight of at least 100 kiloDaltons claimed in claim 21 (in fact Chu et al. specifically disclose a fraction having a molecular weight of 20-25 kiloDaltons). Withdrawal of the rejection is requested.

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CN1047806 was provided only as a one-page entry from Derwent, of which the only relevant information was "Injection compsn. for anal-fistula - comprises Gleditia sinensis, Astragalus membranaceus, Coptis chinensis, and centipede." There is nothing in this disclosure to suggest a purified arabinogalactan composition, far less the arabinogalactan protein composition having a weight average molecular weight of at least 100 kiloDaltons claimed in claim 21. Withdrawal of the rejection is requested.

A search for further information on this reference revealed an abstract in the esp@cenet database, reading: "The present injection is prepd. from a mixture comp. 20-25% Gleditia sinensis, 10-15% Astragalus membranaceus, 5-10% Coptis chinensis, and 7-12% centipede, etc. through boiling at constant temp. with reflux, distilling, boiling with active carbon, cooling, filtering, precipitating, and filtering again. The resultant medical liq. is dissolved with the addition of tween-80 and benzoic-alcohol and the pH value is adjusted. Required injection water is added to the mixture. The product is then steam sterilized at high temp., filled into ampoules and sealed." This further search illustrates that the composition bears no resemblance at all to the claimed composition or method of making it.

Where is this evidence?

EP 0 441 278 discloses new glucanes, referred to by the inventors as "Astraglucanes", and their mixture with other polysaccharides extracted from the roots and rhizomes of *Astragalus membranaceus*. The term "glucane" is not used in English, but "glucan", which is believed to be the intended term, is defined in the *McGraw-Hill Dictionary of Scientific and Technical terms*, 2 ed., as "a polysaccharide composed of the hexose sugar D-glucose". Thus this publication refers to glucose-based polysaccharides and not to arabinogalactan proteins of the type claimed in the present application. While these polysaccharides are disclosed in the publication as having molecular weights between 12,000 and 500,000 Daltons, and Examples 1 and 2 of the publication disclose "glucanes" having a molecular weight above 200,000 Daltons (Astraglucane A) and a mixture of three "glucanes" having molecular weights between 125,000 and 250,000 Daltons (Astraglucane B) respectively, they are distinguished from arabinogalactans (see column 2, lines 6-8) by having a structure consisting of "sequences of 1,3-beta-glucose with a branched arrangement and repeating olygomeric [*sic*] unit." The arabinogalactan proteins of the composition of this invention are highly glycosylated proteins in which the major carbohydrate constituents are arabinose and galactose. The method of preparation of the compounds of the publication, as described in column 2 of the publication, is also chosen to denature proteins; and is thus incapable of preparation of the arabinogalactan protein compositions of the present invention. Withdrawal of the rejection is requested.

Applicants submit that none of the references cited in the Office Action discloses or suggests the arabinogalactan protein composition of the invention, as claimed in claims 21-38; and withdrawal of the rejections is requested.

Conclusion

Entry of the amendment, examination of claims 21-38 as being directed to a single inventive concept within the meaning of PCT Rule 13.1 because they share a common technical feature, withdrawal of the rejections under 35 USC 102(b), and allowance of claims 21-38, are respectfully requested.

Respectfully submitted,

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